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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,568	06/20/2001	John Jianhua Chen	S63.2-9515	8081

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EXAMINER	
HON, SOW FUN	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/885,568	Applicant(s) CHEN ET AL.	
	Examiner Sow-Fun Hon	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *07/12/04* .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Interview Summary

1. In response to applicant's telephone call on July 12,2004, regarding the last Office action mailed July 6, 2004, the following corrective action is taken.

The period for reply of 3 MONTHS set in said Office Action is restarted to begin with the mailing date of this letter.

2. The Office action dated 03/16/04 is non-final, and therefore the incorrect database status of finality of said action is withdrawn.

Response to Amendment

Withdrawn Rejections

3. The 35 U.S.C. 102(b) and 103(a) rejections in the Office action dated 03/16/04 are withdrawn due to Applicant's amendment dated 06/14/04.

New Rejections

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 14, 17, 22-23 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The differentiation between the terms "compliant" and "semicompliant" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356

(CCPA 1976). Although the specification names polyamides and block copolymers comprising polyamide blocks and polyether blocks as belonging to the group of compliant or semi-compliant polymers (page 10, lines 28-31), it does not distinguish between the compliant and the semi-compliant polymers. For the purpose of examination, the two terms are treated as being overlapping terms.

6. Claims 18-20, 22, 23 recite the limitations "layer (A)" and "layer (B)" in claims 18, 20, 22, 23. There is insufficient antecedent basis for these limitations in the claims which depend on the parent claim 14.

Claim Rejections - 35 USC § 103

7. Claims 1-7, 9, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. (previously cited WO 95/18647) in view of Zdrahala (previously cited US 5,248,305), as evidenced by Bland et al. (previously cited US 5,427,842).

Regarding claim 1, Rau et al. has a balloon for a medical device (catheter) (column 1, lines 10-15) comprising a plurality of fibers to provide reinforcement (column 14, lines 25-30). The reinforcing fiber may comprise LCP (liquid crystal polymers) (column 15, lines 1-5). The fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon. This is a specific example of the fibers being distributed in a selected direction relative to the balloon axis. The liquid crystal polymer fiber has greater tensile strength than the thermoplastic polymer matrix, as evidenced by Zdrahala.

Zdrahala teaches that the desired high tensile strength is provided by liquid crystal polymer reinforcement of thermoplastics (column 3, lines 10-25).

Rau et al. teaches that other thermoplastic materials used to make the balloon may include polyurethane (column 1, lines 15-20). Therefore it would have been obvious to one of ordinary skill in the art to have used polyurethane instead of thermoplastic polyimide (column 2, lines 15-20) in order to obtain a balloon with increased compliance.

Polyurethane is a semi-compliant material as evidenced by Bland et al.

Bland et al. teaches that the ductile polymer may be polyurethane or polyamide (column 4, lines 45-55). Applicant's specification teaches that polyamide belongs to the group of "compliant" or "semi-compliant" polymer (page 10, lines 28-31). The term "ductile" thus overlaps the terms "compliant" and "semi-compliant".

Regarding claim 3, Rau et al. teaches that the shaft may be composed of a blend of polymer (polyimide) and liquid crystal (column 16, lines 20-25), and that when the balloon is integral with the shaft (column 14, lines 10-15), the matrix polymer is thermoplastic polymer (polyimide). Thus the balloon is of the same composition as the shaft when it is integral with the shaft, and is composed of a blend of thermoplastic polymer and liquid crystal. As a blend, the liquid crystal polymer fiber reinforcement cores are coextruded with the matrix thermoplastic polymer material (column 14, lines 10-20).

Regarding claims 4-5, Rau et al. teaches that the liquid crystal polymers are rigid, rod-like (column 16, lines 25-30). The liquid crystal rods thus constitute cores of polymeric material which have a bulk elongation of less than 150 % (claim 4). The liquid crystal rods are aligned parallel along the structure (column 15, lines 5-10) which means that they are oriented parallel to

the longitudinal axis of the balloon. Being rigid, the liquid crystal core polymeric material has a bulk elongation less than the matrix material when oriented in the direction of the longitudinal axis (claim 5).

Regarding claim 6, Rau et al. teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30).

Regarding claim 7, Rau et al. teaches that selectively altering the number, arrangement and thickness of the balloon in a variety of configurations provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25).

Regarding claim 12, Rau et al. teaches that the fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon.

Rau et al. fails to teach that the liquid crystal polymer fibers are distributed in the matrix material helically relative to the balloon axis, or that the fibers have a diameter of from 0.01 to about 10 microns.

Zdrahala teaches a catheter tubing which exhibits stiffness in the longitudinal direction as well as rotational stiffness and both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5).

Regarding claims 2, 9, Zdrahala teaches that the liquid crystal fibers are distributed in the matrix material helically relative to the balloon axis (separate phase of liquid crystal plastic forms helical extending, separate fibrils within the extruded tubing with the fibers (fibrils) being dispersed in the structural plastic matrix) (column 5, lines 1-15).

Regarding claim 10, Rau et al. teaches that as a blend, the liquid crystal polymer fiber reinforcement cores are coextruded with the matrix thermoplastic polymer material (column 14, lines 10-20).

Regarding claims 11, 13, Zdrahala teaches that the fibers (fibrils) exhibit an aspect ratio of about 10 to 300, the aspect ratio being defined by the length of the fiber divided by its diameter (column 5, lines 15-25). Thus the claimed range of the LCP (liquid crystal polymer) fiber diameter of from 0.01 to about 10 microns is the result of routine experimentation in order to obtain the desired aspect ratio.

Zdrahala teaches that the helical fibers provide rotational stiffness to the tube (column 8, lines 15-20). Zdrahala thus demonstrates that it would have been obvious to one of ordinary skill in the art to have distributed the liquid crystal polymer fibers in the matrix material helically relative to the balloon axis of Rau et al. in order to provide some rotational stiffness to control the radial expansion of the balloon.

8. Claims 1, 7-8, 14, 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. in view of Bland et al., as evidenced by Zdrahala.

Regarding claim 1, Rau et al. has a balloon for a medical device (catheter) (column 1, lines 10-15) comprising a plurality of fibers to provide reinforcement (column 14, lines 25-30). The reinforcing fiber may comprise LCP (liquid crystal polymers) (column 15, lines 1-5). The fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon. This is a specific example of the fibers being distributed in a selected direction relative to the balloon axis. The

liquid crystal polymer fiber has greater tensile strength than the thermoplastic polymer matrix, as evidenced by Zdrahala.

Zdrahala teaches that the desired high tensile strength is provided by liquid crystal polymer reinforcement of thermoplastics (column 3, lines 10-25).

Rau et al. teaches that other thermoplastic materials used to make the balloon may include polyurethane (column 1, lines 15-20). Therefore it would have been obvious to one of ordinary skill in the art to have used polyurethane instead of thermoplastic polyimide (column 2, lines 15-20) in order to obtain a balloon with increased compliance.

Polyurethane is a semi-compliant material as evidenced by Bland et al.

Bland et al. teaches that the ductile polymer may be polyurethane or polyamide (column 4, lines 45-55). Applicant's specification teaches that polyamide belongs to the group of "compliant" or "semi-compliant" polymer (page 10, lines 28-31). The term "ductile" thus overlaps the terms "compliant" and "semi-compliant".

Rau et al. teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which is composed of a polymer matrix material and LCP (liquid crystal polymer) (column 14, lines 25-30), wherein one embodiment has inner and outer layers of polymer matrix material (thermoplastic polyimide) surrounding an intermediate layer of the blend of polymer matrix material and LCP (column 17, lines 10-15). Selectively altering the number and arrangement of these layers provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25).

Rau et al., however, fails to teach at least 7 layers in an alternating series of fiber-containing and fiber-free layers; or 7 to 50 layers in an alternating series of LCP-containing and LCP-free layers.

Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and not stretch to a larger size (column 1, lines 45-50).

Regarding claims 7-8, 14, Bland et al. teaches a tear-resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials (column 1, lines 10-15) (claim 7). The tear resistant film comprises more than 5 layers and which overlaps the claimed range of at least 7 laminate layers (column 3, lines 30-40) (claim 8), and from more than 5 layers to 35 layers, up to 61 layers (column 6, lines 50-60), which overlaps the claimed range of from 7 to 50 total polymer layers (claim 14).

Rau et al. teaches that selectively altering the number and arrangement of the layers of LCP-reinforced layers with LCP-free layers provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25). The LCP fiber-reinforced layers of Rau et al. are relatively stiff due to the rigidity of the liquid crystal polymer reinforcement (column 16, lines 20-25).

Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size (column 1, lines 45-50). Therefore Bland et al. demonstrates that it would have been obvious to one of ordinary skill in the art to have provided the balloon of Rau et al., with laminate layers comprising from 7 to 50 layers of an alternating series of LCP fiber-containing and LCP fiber-

free layers, in order to obtain an angioplasty balloon with improved tear resistance and controlled inflation dimension.

Regarding claim 16, Rau et al. teaches the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which is composed of a polymer matrix material and LCP (liquid crystal polymer) (column 14, lines 25-30), wherein one embodiment has inner and outer layers of polymer matrix material (thermoplastic polyimide) surrounding an intermediate layer of the blend of polymer matrix material and LCP (column 17, lines 10-15). Hence the single polymer material and the matrix polymer material are the same.

Regarding claims 17, 22, Rau et al. teaches that thermoplastic polyurethane may be used to make the balloon (column 1, lines 15-20). Polyurethane is compliant or semi-compliant, as evidenced by Bland et al.

Bland et al. teaches that the ductile polymer may be polyurethane or polyamide (column 4, lines 45-55). Applicant's specification teaches that polyamide belongs to the group of "compliant" or "semi-compliant" polymer (page 10, lines 28-31). The term "ductile" thus overlaps the terms "compliant" and "semi-compliant".

Regarding claim 23, Bland et al. teaches that the ductile polymer may be polyurethane or polyamide (column 4, lines 45-55), and that the polyamide may be copolymerized with a long chain polyethylene glycol (column 9, lines 1-5) which is a polyether, forming a block copolymer comprising polyamide blocks and polyether blocks.

Regarding claims 18-19, Rau et al. shows in Fig. 16, inner and outer layers of thermoplastic polymer surrounding an intermediate layer comprising a blend (column 5, lines 15-20). The single polymer layers (A) are thicker than the intermediate blend layer (B). Rau et

al. teaches that selectively altering the thickness, number and arrangement of these layers provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25). Thus the claimed ratio A/B of the total thickness of the two types of layers (A) and (B) respectively, of from about 5 to about 15 (claim 18), and of from about 8 to about 10 (claim 19), is the result of routine experimentation, in order to obtain the desired compliance characteristics.

Regarding claim 21, Rau et al. teaches that the fibers are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon.

Regarding claim 20, Rau et al. teaches a prior art matrix polymer material which is polyurethane (column 1, lines 15-20). Rau et al. fails to teach that the LCP polymer is present in the blend in an amount of from about 5 to about 25 % by weight.

Zdrahala teaches that the composition of a catheter tubing can contain from 5 to 35 weight percent of the LCP (liquid crystal polymer), and that the matrix of the blend may be composed of polyurethane (column 4, lines 15-35). The range is within the claimed range of from about 5 to about 25 % by weight.

Zdrahala demonstrates that the claimed range is the result of routine experimentation with the LCP blend of Rau et al. in order to obtain a balloon catheter with the desired reinforcement.

Response to Arguments

9. Applicant's arguments with respect to claims 1-14, 16-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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07/15/04

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1772
7/23/04